

U.S. Serial No. 10/612,082
Filed: July 2, 2003

P8792.05

REMARKS

Election/Restriction

The Examiner's comments have not addressed the points raised by Applicants in their previous response, namely (1) the inconsistency in the restriction requirements made in the parent case (Serial No. 09/434,649), the first divisional (Serial No. 09/757,527) and the present application (Serial No. 10/612,082); and (2) why it would be a serious burden to search all of the method claims when they are all classified by the Examiner in the exact same class and subclass. However, in the interest of furthering prosecution of this application on the merits, Applicants cancel claims 54-102, without prejudice to the filing of future divisional or continuation applications directed thereto.

Claim Rejections - 35 U.S.C. §102

Applicants have amended independent claim 103 to clarify that the open-cell structure of the foamed graft is produced by means of reticulating and optionally annealing. Support for this amendment can be found, for example, on page 14, lines 25-26 of the application as originally filed.

The Examiner rejected claims 103-112 under 35 USC 102(b) as being anticipated by Brunell et al. (U.S. Patent No. 5,314,925). Applicants respectfully traverse the rejection.

Brunell et al. disclose a process for producing thermoplastic foam articles, using an aromatic polycarbonate resin and a polytetrafluoroethylene nucleating agent. The only process disclosed in Brunell et al. for forming such articles is injection molding (see, e.g., '925 Patent at column 4, line 22 et seq.), and the only example in the patent explicitly employs injection molding (see '925 Patent at column 6, line 52). The resulting articles produced by Brunell et al.'s injection molding process have an external skin (see, e.g., '925 Patent at column 4, line 41 ("external skin") and column 4, lines 54-55 ("skin layer")).

U.S. Serial No. 10/10/612,082
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On the contrary, the present invention relates to a method of forming prostheses by extruding a thermoplastic elastomer with the aid of a blowing agent, thereby producing a foamed graft, and thereafter reticulating and optionally annealing the foamed graft to effect an open-cell structure. As an initial matter, the present invention involves extrusion of thermoplastic elastomers, in contrast to the injection molding process disclosed in Brunell et al.

Moreover, Brunell et al. nowhere discloses reticulating the foam articles to effect an open-cell structure as in the present invention, and the Examiner has not indicated where in Brunell et al. reticulation is disclosed or even suggested. As disclosed on page 15 of the present specification, various types of post-treatment exist for converting closed cell foams to open cell foams, and that “[r]eticulation, removal of possible interior and /or exterior skin, and other post production techniques may be employed to produce the open-cell porosities needed for the ingrowth of living tissue.” In contrast, as noted above, the resulting articles from Brunell et al.’s injection molding process all possess an external skin. That skin is not removed from the articles made according to Brunell et al.’s method and no post production technique, i.e., reticulation or otherwise, is disclosed by Brunell et al. to effectuate its removal. In fact, the external skin that remains on the articles would prevent the “uninterrupted tissue and vessel ingrowth” contemplated by the present invention’s open-cell structure (see, e.g., page 3, lines 16-17). Moreover, Brunell et al. is silent with respect to the openness of the internal foam structure generated through the injection molding process (other than a general characterization of uniformity of cell structure). That omission, coupled with Brunell et al.’s failure to disclose any post production technique, including reticulation, removes Brunell et al. as an anticipatory reference to the present pending claims, which recite “reticulating” ... “the foamed graft to effect an open-cell structure.”

Finally, even if Brunell et al. had disclosed extrusion and reticulation, which it does not, Brunell et al. nowhere discloses annealing the foam articles after they are produced. Brunell et al. only discloses heating during the molding process itself to create the foam in the first instance (see, e.g., ‘925 Patent at column 5, lines 11-14

U.S. Serial No. 10/10/612,082
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(“During processing the blowing agent is exposed to sufficient heat to cause it to decompose thus giving off the gases necessary to achieve the foaming process.”)).

In light of the above comments, Applicants believe that the rejection over Brunell et al. has been overcome, and respectfully request that the rejection over Brunell et al. be withdrawn and the claims proceed to issuance.

The Examiner is encouraged to contact the attorney of record at the telephone number listed below if there are any further questions.

Respectfully submitted for,

Zilla, et al.

Date: April 10, 2006



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